Please cancel claims 1-16 and 25-49, without prejudice.

Remarks

Claims 1-49 are pending in the application. Claims 1-16, 19-22, and 25-49 have been withdrawn from consideration. Claims 17, 18, 23, and 24 stand rejected. Claim 17 has been amended, and claims 1-16 and 25-49 have been canceled. New claims 51-60 have been added. No new matter is added to the Specification by these changes. Applicant respectfully requests reexamination and reconsideration of the case, as amended. Each of the rejections levied in the Office Action is addressed individually below.

I. Rejection under 35. U.S.C. § 102(b), as being anticipated by Hubbell *et al.* (U.S. Patent 5,410,016). Claims 17-18 and 23-24 stand rejected under 35 U.S.C. § 102(b), as being anticipated by Hubbell *et al.* (U.S. Patent 5,410,016). Examiner states that Hubbell *et al.* teach a "method of drug delivery comprising applying a biologically active substance to tissue surfaces of a patient with crosslinked macromers" using thermal polymerization. Applicant submits that Hubbell *et al.* do not teach such a method because Hubbell *et al.* do not provide an enabling disclosure for such a method using thermal polymerization to polymerize the delivered macromers. Instead all the examples in the '016 patent use photopolymerization. Nowhere in the patent is described a functional system using a thermal polymerization initiator and thermal energy to effect polymerization. Applicant submits that since an enabling disclosure is required in order for a reference to anticipate the rejected claims, the rejection under § 102(b) must be removed.

The independent claim 17 has also been amended to recite that the thermal polymerization initiator is selected from the group consisting of 2,2'-azobis-[N,N'-dimethyleneisobutyramidine] and derivatives of 2,2'-azobis-[N,N'-dimethyleneisobutyramidine] dihydrochloride. Hubbell *et al.* do not teach the use of such compounds as thermal

polymerization initiators. The only compounds they mention as potential thermal polymerization initiators are potassium persulfate, benzoylperoxide, and ammonium persulfate (col. 9, line 65-col. 10, line 2). As described on page 10, lines 16-21 of the present application, the azo-based initiators recited in claim 17 have the advantages of having limited toxicity, being extremely water soluble, and initiating polymerization at temperatures around 37°C, body temperature.

Given the differences between the claimed invention and the lack of enabling disclosure of Hubbell *et al.*, Applicant respectfully requests that the rejection be removed, and the claims be allowed.

II. **New claims.** New claims 50-61 and the amendment to claim 17 are supported by the originally filed claims 2-16. These new claims are the original claims re-written to depend from claim 17. Since this subject matter was included in the application as filed and would be appreciated by one of skill in the art as an aspect of the present invention, Applicant submits that no new matter has been added to the application by the addition of new claims 50-61 or the amendment to claim 17 reciting specific thermal polymerization initiators.

In view of the forgoing arguments, Applicant respectfully submits that the present case is now in condition for allowance. A Notice to that effect is requested.

Please charge any fees that may be required for the processing of this Response, or credit any overpayments, to our Deposit Account No. 03-1721.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, D.C. 20231
on 12-6-02

Appendix A

Clean Copy of Claims as Amended

17. (Amended) A method of drug delivery, the method comprising the steps of:

introducing a polymerizable material (prepolymer), a thermal polymerization initiator selected from the group consisting of 2,2'-azobis-[N,N'-dimethyleneisobutyramidine] dihydrochloride and derivatives of 2,2'-azobis-[N,N'-dimethyleneisobutyramidine] dihydrochloride, and a diagnostic, therapeutic, or prophylactic agent into an animal's body; and

applying thermal energy transdermally for a sufficient amount of time to polymerize or crosslink the said prepolymer, or allowing the pre-polymer to polymerize or crosslink using only the animal's own body heat as a thermal energy source.

18. The method of claim 17 wherein the step of providing an agent comprises providing a bioactive agent.

19. The method of claim 17 wherein the step of providing an agent comprises providing a protein.

20. The method of claim 17 wherein the step of providing an agent comprises providing a peptide.

21. The method of claim 17 wherein the step of providing an agent comprises providing a

vaccine.

22. The method of claim 17 wherein the step of providing an agent comprises providing a polynucleotide.

23. The method of claim 17 wherein the step of providing an agent comprises providing an organic compound.

24. The method of claim 17 wherein the step of providing an agent comprises providing an agent within a microsphere.

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50. (New) The method of claim 17 wherein the polymerizable material is biodegradable before and after polymerization.

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51. (New) The method of claim 17 wherein the polymerizable material has unsaturated functional groups.

52. (New) The method of claim 17 wherein the polymerizable material has functional groups selected from the group consisting of acroyl, methacroyl, allyl, and vinyl.

53. (New) The method of claim 17 wherein the polymerizable material is a hydrogel.

54. (New) The method of claim 17 wherein the polymerizable material and thermal initiator are covalently linked together.

55. (New) The method of claim 17 wherein the step of introducing comprises introducing the material and initiator under the skin, into a muscle, into a body cavity, into a potential space, or into an organ.

56. (New) The method of claim 17 wherein the thermal polymerization initiator initiates polymerization between 37°C and 45°C.

57. (New) The method of claim 17 wherein the thermal polymerization initiator is water soluble.

58. (New) The method of claim 17 wherein the thermal polymerization initiator has limited toxicity in animals.

59. (New) The method of claim 17 wherein the step of introducing comprises injecting said prepolymer and said initiator using a syringe.

60. (New) The method of claim 17 wherein the step of introducing comprises placing said prepolymer and said initiator during a surgical procedure.

61. (New) The method of claim 17 wherein the step of applying thermal energy comprises applying thermal energy from a heat source selected from the group consisting of a heating pad, a water bath, a hot water bottle, a heat lamp, and a light.

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